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EXAMINER	
TRAVERS, RUSSELL S	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 20040816

Application Number: 09/839,366
Filing Date: April 23, 2001
Appellant(s): ETIENNE, MARIE-CHRISTINE

Richard E. Fichter
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed June 1, 2004.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 1-22 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

Clairet et al, 0 315 552 A1, EPO, Issued 10 May 1989

Tetau, Max, 118CA:175783, 1992, based on French Patent #2,676,648 issued 27 November 1992

Petit et al, Biosis87 :1200988, citing Human Toxicology, vol. 8(2), pages 125-130, 1989.

Cazin et al, Biosis 87:385871, citing Human Toxicology, vol. 6(4), pages 315-320, 1987.

Besnouin, Didier, WO 89/ 00858 A1, issued 9 February 1989

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-22 are rejected under 35 U.S.C. § 101 because the claimed invention, setting forth and incredible utility, lacks patentable utility.

The instant application contains an invention directed to treating various conditions with compounds capable of producing the observed symptomology; wherein these compounds are administered at undetectable levels. Applicants have supplied only anecdotal evidence supporting the therapy herein claimed. It is noted that Petit et al (provided in parent) and Labrecque et al published studies employing the same manner of therapy herein claimed and found no therapeutic benefit residing therein. The skilled artisan would view a randomized, double-blind, placebo-controlled clinical trial more convincing than antidotal accounts related by Applicants. Absent information, as well grounded as that provided by Examiner cited prior art, the instant claims fail to illustrate the presence of identifiable utility.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, and thereby failing to provide an enabling disclosure.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art

7) the predictability of the art, and

8) the breadth of the claims.

Applicant fails to set forth the criteria that defines either "active principle, R", or, those compounds that are "a poison, or part of a poison". Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a limited number of "active principle, R", or, those compounds that are "a poison, or part of a poison" examples are set forth,

thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all "active principle, R", or, those compounds that are "a poison, or part of a poison", necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Claims 1-11, 13-19 and 20-22 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 1-11, 13-19 and 20-22 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-11, 13-19 and 20-22 are rendered indefinite by the phrases "active principle, R", or, those compounds that are "a poison, or part of a poison" and thereby failing to clearly set forth the metes and bounds of the patent protection desired. Criteria defining "active principle, R", or, those compounds that are "a poison, or part of a poison" are not set forth in the specification, thereby failing to provide information defining the instant inventions metes and bounds. Applicant's term fails to clearly define the subject matter encompassed by the instant claims, thus is properly rejected under 35 USC 112, second paragraph.

Claims 1-22 are rejected under 35 U.S.C. § 103 as being unpatentable over Labrecque et al Tetau and Applicants' admission on the record, all of record.

Labrecque et al and Tetau teach the homeopathic compounds herein claimed in combination with various pharmaceutical carriers and excipients in a dosage form, specifically divalent metal ions. These medicaments are taught as useful for treating viral diseases. Claims 1-22, and the primary reference, differ as to:

1) the metal ion employed, and

2) the proposed mechanism by which the homeopathic therapy effected the desired therapeutic regimen.

The first deficiency is cured by Tetau teaching employment of divalent metal ions to effect the desired therapeutic goals. The second deficiency is cured by cured by Applicants' admission that the xCH factor effects the therapy in a similar and predictable way. Thus, the skilled artisan possessing the "Hahnemannian homeopathic dilution (xCH)", or "Korsakowian homeopathic dilution (xCH)" would possess the knowledge to effect the required therapy, and be motivated to apply such therapy, regardless the etiology.

As stated in the instant specification, determining the active ingredient dosage level required to effect optimal therapeutic benefit is well within the Skilled Artisan's purview and the benefits of achieving such maximization obvious, to said skilled artisan. The claims merely recite the obvious employment of old and well known active ingredients, carriers and excipients.

Claims 1-22 are rejected under 35 U.S.C. § 103 as being unpatentable over Cazin et al, Besnouin and Applicants' admission on the record, all of record.

Cazin et al and Besnouin teach the homeopathic compounds herein claimed in combination with various pharmaceutical carriers and excipients in a dosage form, specifically arsenic compounds. These medicaments are taught as useful for producing the retention of, or causing excretion of compounds responsible for disease. Claims 8-28, and the primary reference, differ as to:

1) the metal ion employed, and

2) the proposed mechanism by which the homeopathic therapy effected the desired therapeutic regimen.

The first deficiency is cured by information possessed by the skilled artisan and Besnouin teaching the employment of calcium ions to effect the desired therapy. Additionally, Cazin teaches effecting the desired therapeutic goal by employing arsenic, residing in the same chemical period as the claimed antimony. The skilled artisan would have expected compounds residing in the same chemical period to possess therapeutically equivalent effects. The second deficiency is cured by cured by Applicants' admission that the xCH factor effects the therapy in a similar and predictable way. Thus, the skilled artisan possessing the "Hahnemannian homeopathic dilution (xCH)", or "Korsakowian homeopathic dilution (xCH)" would possess the knowledge to effect the required therapy, and be motivated to apply such therapy, regardless the etiology.

As stated in the instant specification, determining the active ingredient dosage level required to effect optimal therapeutic benefit is well within the Skilled Artisan's purview and the benefits of achieving such maximization obvious, to said skilled artisan. The claims merely recite the obvious employment of old and well known active ingredients, carriers and excipients.

(11) Response to Argument

The rejection under 35 U.S.C. § 101 is proper because the claimed invention, setting forth and incredible utility, lacks patentable utility: this rejection should be maintained. Examiner believes the Labrecque et al teaching provides a basis for maintaining the instant rejection for setting forth an incredible utility. Attention is directed to Labrecque et al (page 1751, column 1, paragraph 1) teaching "the lack of published studies providing evidence of the efficacy of homeopathic drugs". This study addresses this lack of information by assessing efficacy of these therapies in a properly controlled double blind clinical study. At this study's end, the Authors concluded the "homeopathic treatment studied was as effective as the placebo" illustrating a lack of patentable utility in the claimed subject matter. If a double blind, properly controlled, clinical study illustrating efficacy in homeopathic therapies is known to the Appellant, Examiner would welcome such an illustration of therapeutic efficacy. Absent a showing, the instant claims are illustrated by Labrecque et al as failing to provide a patentable utility, rendering the instant claims fatally flawed under 35 U.S.C. § 101 because the claimed invention, setting forth and incredible utility, lacks patentable utility.

That Appellant's European application was published on December 29, 1997 is not germane to the instant rejection. First, this grant was published under a statutory system very different from those statutes at issue. Second, a patent is property, not legal precedent, as constructively averred by Appellant. Issuance of a European patent publication is not an assurance of that claimed inventions validity. Examiner notes claims 1-22 are rejected under 35 U.S.C. § 101 as failing to set forth a credible utility, thus, lacking patentable utility. Therefore, claim 12 is also rejected under 35 U.S.C. § 101 because this claim fails to set forth a credible utility, and thus, lacks patentable utility.

The objection to the specification, and the rejection of claims 1-11 and 13-22 under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, and thereby failing to provide an enabling disclosure is proper, and should be maintained. The presented claims read on effecting various biochemical processes, which may, or may not, be related to treating a disease. Examiner notes claim 12, reciting a viral disease, is not included in the instant rejection. Simply stated, Appellant claims a function hoped to be effected, and thereby failing to provide information required to practice the invention as claimed. A nexis between the instant recited biochemical effects, and any treatable disease is not taught. Examiner notes claim 12 is not included in the instant objection, or rejection, rendering rebuttal arguments with respect to claim 12 moot. Claim 12 presents additional concrete limitations, and thus, is not functional at the point of novelty, as are those rejected claims 1-11 and 13-22.

Examiner finds arguments rebutting the rejection under 35 USC 112, first and second paragraph unconvincing. Attention is directed to *General Electric Company v. Wabash Appliance Corporation et al* 37 USPQ 466 (US 1938), at 469, speaking to functional language at the point of novelty as herein employed: "the vice of a functional claim exists not only when a claims is "wholly" functional, if that is ever true, but when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty". Functional language at the point of novelty, as herein employed by Applicants, is further admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC 1997) at 1406: stating this usage does "little more than outlin[e] goals appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate". Appellant's functional language at the point of novelty fails to meet the requirements set forth under 35 USC 112, first, and second paragraph. Claims employing functional language at the point of novelty, such as Applicants', neither provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limits of the monopoly asserted" *General Electric Company v. Wabash Appliance Corporation et* supra, at 468. Claims thus constructed provide no guidance as to medicaments employed, levels for providing therapeutic benefit, or provide notice for those practicing in the art, limits of protection. Simply stated, the presented claims are an invitation to experiment, not reciting a specific medicament regimen useful for practicing the instant invention.

Appellant claims some "active principle R", wherein "active principle R" is not specifically set forth as a closed set for compounds in the presented specification, thereby failing to establish the instant inventions metes and bounds Thus, "active principle, R", or, those compounds that are "a poison, or part of a poison" are only bounded by the imagination of the Appellant, not those limitation examples recited in the instant specification. That Appellant envisions one, or another, compound useful for practicing the claimed invention, fails to establish metes and bounds for the presented claims.

Rejection of claims 1-22 under 35 U.S.C. § 103 is proper, and should be maintained. Examiner agrees there should be a reasonable expectation of success, and all limitations must be addressed. In the instant case, attention is directed to Labrecque et al teaching administration of a 7CH Hahnemannian dilution of antimony for treating viral disease (see page 1751, column 1, paragraph 3). Labrecque et al teach this therapeutic regimen as equivalent to the placebo, thus, providing an expectation of therapeutic success. This prior art therapeutic regimen differs from the instant claimed regimen by failing to recite the biochemical steps proposed as effecting the desired therapeutic benefit. If an identical prior art therapeutic agent is administered in the prior art, in an identical manner, to effect the identical therapeutic endpoint; the prior art invention, and the claimed invention are the same. Appellant attempts, in the instant case, to distance the claimed invention from the prior art by including hypothetical biochemical process steps in the instant claims.

Appellant's arguments with regard to the Labrecque et al teachings are fatally flawed for several independent reasons. First, Labrecque et al actually treated a viral disease, planar warts, with those therapeutic regimens herein claimed. As stated above, attention is directed to Labrecque et al teaching administration of a 7CH Hahnemannian dilution of antimony for treating viral disease (see page 1751, column 1, paragraph 3). Examiner notes the instant claims are employing the connector "comprising" which allows inclusion of any number of active ingredients. Second, those antiviral therapies, herein envisioned in claim 12, are not limited to specific compounds as Appellant argues, but are directed to any compound under the sun, as recited in claim 1. Third, the presented arguments are not based on any limitations herein claimed, and are therefore moot.

Appellant's rebuttal arguments with regard to Tetau are unconvincing. A simple perusal of Tetau (page 1, paragraphs 1 and 3) respectively teach antiviral homeopathic therapies employing divalent metal ions. As to the "preterbed pericellular transport system", envisioned as mediating the therapeutic benefit: if the therapeutic benefit taught by the Examiner cited prior art is provided by those regimens herein claimed, those systems involved in such therapy must have been effected in the manner envisioned to reach this same endpoint as claimed herein. The instant claims are directed to effecting a biochemical pathway with an old and well known therapeutic regimen. Arguments that Applicant's claims are not directed to the old and well known ultimate utility for this therapy are not probative. It is well settled patent law that mode of action elucidation fails to impart patentable moment to otherwise old and obvious

subject matter. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not cause a claim drawn to those things to distinguish over the prior art.". Additionally, where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter, may in fact be an inherent characteristic of the prior art, it possesses the authority to requires the applicant to prove that the subject matter shown to be in the prior art dose not posses the characteristic relied on. In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical intermediates. The ultimate utility for the claimed compounds is old and well known, rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103. The sole distinction between the claimed, and prior art invention resides in the recitation of various poorly described biochemical pathways previously unknown to Examiner during his tenure as an Examiner, research scientist , or graduate student in biochemistry. Those therapies herein claimed have been tried many times, with the sole distinction from the prior art being an apparent discovery of some mode by which this therapy might be effected. "(O)bvious to try" rebuttal arguments simply fail to address the facts of the instant rejection.

Rebuttal arguments presented to overcome the rejection of claims 1-22 under 35 U.S.C. § 103 as being unpatentable over Cazin et al, Besnouin and Applicants'

admission on the record, all of record, are unconvincing. Attention is directed to Besnouin (page 1, paragraph 1 and page 4, table 2) respectively, teaching homeopathic antiviral therapy employing calcium, that divalent metal ion herein claimed, and phosphorus. Examiner notes Arsenic and Phosphorus reside in the same period, thus possess equivalent chemical properties, thus obviating these compounds use for the same utility. In the instant case, this issue need not be reached. As stated above, Besnouin (page 1, paragraph 1 and page 4, table 2) respectively, teach homeopathic antiviral therapy employing calcium, that divalent metal ion herein claimed and phosphorus. To teach Arsenic for this homeopathic antiviral use as residing in the prior art is a "make weight". Calcium and Phosphorus, two of the three recited Markush members are taught by Besnouin (page 1, paragraph 1 and page 4, table 2) respectively as useful in homeopathic antiviral therapy, thus, obviating the use herein claimed.

Appellant urges the instant invention is rendered unobvious by the recitation of "preterbed pericellular transport system" in the presented claims; this rebuttal argument is unconvincing. As stated above, the "preterbed pericellular transport system", envisioned as mediating the therapeutic benefit: if the therapeutic benefit is provided by those regimens herein claimed, those systems involved in such therapy must have been effected in the manner envisioned. The instant claims are directed to effecting a biochemical pathway with an old and well known therapeutic regimen. Arguments that Applicant's claims are not directed to the old and well known ultimate utility for this therapy are not probative. It is well settled patent law that mode of action elucidation

fails to impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not cause a claim drawn to those things to distinguish over the prior art.". Additionally, where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter, may in fact be an inherent characteristic of the prior art, it possesses the authority to requires the applicant to prove that the subject matter shown to be in the prior art dose not posses the characteristic relied on. In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical intermediates. The ultimate utility for the claimed compounds is old and well known, rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103.

Appellant is attempting to recapture various homeopathic remedies popular in the 18th century by the recitation of "preterbed pericellular transport system", envisioned as mediating the claimed therapeutic benefit. Absent some limitation in the **claimed** invention distancing the envisioned invention from the prior art, the instant claims must remain rejected as obvious over the prior art of record.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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rst
August 18, 2004

Conferees

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